



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,186	05/09/2000	JYUNJI YOSHII	07898-056001	6553

7590

11/28/2003

Stanley P. Fisher
Reed Smith LLP
3110 Fairview Park Drive
Suite 1400
Falls Church, VA 22042

EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
----------	--------------

1634

DATE MAILED: 11/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/554,186	YOSHII ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,8,10-19,21-27 and 29-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,8,10-19,21-27 and 29-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 9 September 2003 in which claims 1 and 26 were amended, claim 28 was canceled and claim 31 was added.

All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action dated 9 June 2003 are withdrawn in view of the amendments.

All of the arguments have been thoroughly reviewed and are discussed below. New grounds for rejection necessitated by amendment are discussed.

Claims 1, 3-5, 8, 10-19, 21-27 and 29-31 are under prosecution.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3-5, 8, 10-19, 21-24, 26-27, 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nova et al (U.S. Patent No. 6,284,459 B1, filed 5 September 1996) in view of Kercso et al (U.S. Patent No. 6,132,685, filed 10 August 1998).

Art Unit: 1634

Regarding Claim 1, Nova et al disclose a biochip comprising a surface spotted with a plurality of biopolymers in a predetermined pattern i.e. matrix and a storage medium for storing information of the biopolymers to be spotted i.e. memory (Column 7, lines 6-65 and Fig. 22-30) wherein the storage medium stores information comprising spot location, identity of the biopolymers spotted on each spot location and the amount of biopolymers binding sites on each spot (Column 8, lines 42-47; Column 14, lines 47-65; Column 23, lines 47-56; and Column 91, line 50-Column 92, line 7) and further comprising a looped antenna wherein the storage medium is a IC memory connected to the looped antenna and the storage medium being capable of reading/writing information in a non-contact state (Column 68, line 53-Column 69, line 61).

While Nova et al do not specifically teach the stored information comprises location, identity and amount of biopolymer, they clearly suggest the claimed information is stored or desired (Column 8, lines 42-47; Column 14, lines 47-65).

Furthermore, biochips comprising the claimed storage medium and stored information comprising spot location, identity of the biopolymers, and amount of biopolymers were known in the art at the time the claimed invention was made as taught by Kercso et al (Column 8, lines 23-38) who further teach that their management station comprising the storage medium provides for analysis of a large number of biopolymers (Abstract and Column 3, line 66-Column 4, lines 13). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the storage medium storing information of spot location, identity of the biopolymer and amount of the biopolymer as taught by Kercso et al to the storage medium of Nova et al to thereby provide for the analysis of a large number of biopolymers as taught by Kercso et al (Abstract and Column 3, line 66-Column 4, lines 13).

The claim has been amended to recited "detected amount of biopolymer". The claim is drawn to a product (i.e. biochip). The courts have stated that patentability of a product is not dependent upon the process of making the product, but instead depends on the resulting

Art Unit: 1634

product. Because Kercso et al teach that the stored information included the amount of biopolymer, the instantly claimed “detected amount” is either the same or obvious over that of Kercso et al.

“[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113.

Regarding Claim 3, Nova et al disclose the biochip wherein the surface and the storage medium are detachable i.e. the memory and matrix are pressed to fit into the well and are therefore detachable (Column 41, line 55-Column 42, line 8 and Fig. 22-30).

Regarding Claim 4, Nova et al disclose the biochip wherein the surface and the storage medium are formed integrally i.e. the memory and matrix are bonded into the well and are therefore formed integrally (Column 41, line 55-Column 42, line 8 and Fig. 22-30).

Regarding Claim 5, Nova et al disclose the biochip wherein the storage medium comprises a semiconductor memory which can read/write information in a non-contact state (Column 57, lines 28-58).

Regarding Claim 8, Nova et al disclose a method of using a biochip comprising applying a sample to the biochip wherein the biochip comprises a surface spotted with a plurality of biopolymers in a predetermined pattern the biochip further comprising a looped antenna wherein the storage medium is a IC memory connected to the looped antenna and the storage medium being capable of reading/writing information in a non-contact state (Column 68, line 53-Column 69, line 61); detecting a spot location where the sample has bound wherein the biochip comprises a storage medium that stores information of spot locations in relation to information of spotted biopolymers; and storing and displaying information of the biopolymer that has bound with a sample by searching the data stored in the storage medium based on

Art Unit: 1634

the spot location bound with sample molecule (Column 14, lines 47-65) wherein the storage medium stores information comprising spot location, identity of the biopolymers spotted on each spot location and the amount of biopolymers spotted on each spot (Column 8, lines 42-47; Column 14, lines 47-65; Column 23, lines 47-56; and Column 91, line 50-Column 92, line 7).

While Nova et al do not specifically teach the stored information comprises location, identify and amount of biopolymer, they clearly suggest the claimed information is stored or desired (Column 8, lines 42-47; Column 14, lines 47-65).

Furthermore, biochips comprising the claimed storage medium and stored information were known in the art at the time the claimed invention was made as taught by Kercso et al (Column 8, lines 23-38) who further teach that their management station comprising the storage medium provides for analysis of a large number of biopolymers (Abstract and Column 3, line 66-Column 4, lines 13). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the storage medium storing information of spot location, identity of the biopolymer and amount of the biopolymer as taught by Kercso et al to the storage medium of Nova et al to thereby provide for the analysis of a large number of biopolymers as taught by Kercso et al (Abstract and Column 3, line 66-Column 4, lines 13).

The claim has been amended to recite that the biochip used in the method comprises a "detected amount of biopolymer". The claim is drawn to the use of a product (i.e. biochip). The courts have stated that patentability of a product is not dependent upon the process of making the product, but instead depends on the resulting product. Because Kercso et al teach that the stored information included the amount of biopolymer, the instantly claimed "detected amount" is either the same or obvious over that of Kercso et al.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is

Art Unit: 1634

unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113.

Regarding Claim 10, Nova et al disclose the biochip wherein the storage medium further comprises a covered surface (Column 31, lines 40-45 and Column 32, lines 22-38).

Regarding Claim 11, Nova et al disclose the covered surface comprises a plastic or glass (Column 31, lines 40-45 and Column 32, lines 22-38).

Regarding Claim 12, Nova et al disclose the covered surface protects the storage medium for exposure to a solution (Column 32, lines 22-27).

Regarding Claim 13, Nova et al disclose the biochip further comprising a semiconductor memory support (Column 50, lines 34-45).

Regarding Claim 14, Nova et al disclose the biochip wherein the semiconductor memory support comprises a silicon wafer i.e. chip (Column 19, lines 63-67).

Regarding Claim 15, Nova et al disclose the semiconductor memory support is covered (Column 32, lines 22-38).

Regarding Claim 16, Nova et al disclose the semiconductor memory support is covered with a resin i.e. agarose (Column 32, lines 32-38).

Regarding Claim 17, Nova et al disclose the semiconductor memory support is the surface spotted with the biopolymer (Column 8, lines 58-62 and Column 19, lines 63-67).

Regarding Claim 18, Nova et al disclose the biochip wherein the biopolymer comprises DNA (Column 24, lines 8-19).

Regarding Claim 19, Nova et al disclose the biochip wherein the biopolymer comprises a protein (Column 24, lines 8-19).

Regarding Claim 20, Nova et al disclose the biochip wherein the information stored in the storage medium comprises the amount of biopolymer (Column 14, lines 54-60).

Regarding Claim 21, Nova et al disclose the method of Claims 7 and 8 wherein the biopolymer comprises DNA (Column 24, lines 8-19).

Art Unit: 1634

Regarding Claim 22, Nova et al disclose the method of Claims 7 and 8 wherein the biopolymer comprises a protein (Column 24, lines 8-19).

Regarding Claim 23, Nova et al disclose the biochip further comprising a case member (i.e. well) wherein the surface and the storage medium are detachable from the case member i.e. the memory and matrix are pressed to fit into the well and are therefore detachable from the well (Column 41, line 55-Column 42, line 8 and Fig. 22-30).

Regarding Claim 24, Nova et al disclose the biochip further comprising a case member (i.e. well) wherein the surface and the storage medium are formed integrally with the case member i.e. the memory and matrix are bonded into the well and are therefore formed integrally with the well (Column 41, line 55-Column 42, line 8 and Fig. 22-30).

Regarding Claim 26, Nova et al disclose a method of manufacturing a biochip comprising providing a substrate comprising a looped antenna wherein the storage medium is a IC memory connected to the looped antenna and the storage medium being capable of reading/writing information in a non-contact state (Column 68, line 53-Column 69, line 61), spotting a plurality of biopolymers on a surface of the biochip in a predetermined pattern and writing information of the spot locations to the integrated circuit and associating it with the information of biopolymers on the spot locations (Column 91, line 15-Column 92, line 14).

While Nova et al do not specifically teach the stored information comprises location, identify and amount of biopolymer, they clearly suggest the claimed information is stored or desired (Column 8, lines 42-47; Column 14, lines 47-65).

Furthermore, biochips comprising the claimed storage medium and stored information were known in the art at the time the claimed invention was made as taught by Kercso et al (Column 8, lines 23-38) who further teach that their management station comprising the storage medium provides for analysis of a large number of biopolymers (Abstract and Column 3, line 66-Column 4, lines 13). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the storage medium storing information of

Art Unit: 1634

spot location, identity of the biopolymer and amount of the biopolymer as taught by Kercso et al to the storage medium of Nova et al to thereby provide for the analysis of a large number of biopolymers as taught by Kercso et al (Abstract and Column 3, line 66-Column 4, lines 13).

Nova et al teach that their method includes testing the biopolymers to determine the accuracy and purity of biopolymers are each spot (Column 99, lines 1-39). While they do not specifically teach the claimed "detected amount", it would have been obvious to one of ordinary skill in the art that the testing of Nova et al would require detecting. Furthermore, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply known detection methods to determine the quantity in the method of Kercso et al for the obvious benefits of accurately storing quantity of biopolymer as required by Kercso et al.

It is noted that the claim is drawn to a method of manufacturing a biochip including writing into the memory a detected amount of biopolymer. The claim does not require a detection step. The claim does not require that the detection be performed before, during or after biochip production. The claim merely requires that the amount of biopolymer is a detected amount. For these reasons, the testing of Nova et al in view of the teaching of Kercso et al is clearly encompassed by the instantly claimed detected amount.

Regarding Claim 27, Nova et al disclose a method of Claim 8 wherein the applying step hybridization occurs between the sample and biopolymers spotted on the biochip to provide biopolymers bound with the (Column 74, lines 36-67; Column 91, line 44-Column 92, line 27; and Column 100, lines 46-63).

Regarding Claims 29 and 30, Nova et al disclose the method of Claim 8 wherein the information on the storage medium is searched and displayed (Example 4, Columns 111-112) but they do not specifically teach that the information searched and displayed comprises the amount of the biopolymer or amount of the bound biopolymer (Column 8, lines 42-47; Column 14, lines 47-65).

Art Unit: 1634

However, biochips comprising the claimed storage medium and stored information were known in the art at the time the claimed invention was made as taught by Kercso et al (Column 8, lines 23-38) who further teach that their management station comprising the storage medium provides for analysis of a large number of biopolymers (Abstract and Column 3, line 66-Column 4, lines 13). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the storage medium storing information of spot location, identity of the biopolymer and amount of the biopolymer as taught by Kercso et al to the storage medium of Nova et al to thereby provide for the analysis of a large number of biopolymers as taught by Kercso et al (Abstract and Column 3, line 66-Column 4, lines 13).

4. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nova et al (U.S. Patent No. 6,284,459 B1, filed 5 September 1996) in view of Kercso et al (U.S. Patent No. 6,132,685, filed 10 August 1998) as applied to Claim 1 above and further in view of Fodor et al (U.S. Patent No. 5,800,992, issued 1 September 1998).

Regarding Claim 25, Nova et al teach the biochip comprising a surface spotted with a plurality of biopolymers in a predetermined pattern i.e. matrix and a storage medium for storing information of the biopolymers to be spotted i.e. memory (Column 7, lines 6-65 and Fig. 22-30) wherein the storage medium stores information comprising spot location, identity of the biopolymers spotted on each spot location and the amount of biopolymers spotted on each spot (Column 8, lines 42-47; Column 14, lines 47-65; Column 23, lines 47-56; and Column 91, line 50-Column 92, line 7) wherein the biochip comprises arrayed spots of high density (Column 7, lines 12-50) but they do not specifically teach a density of 10,000 spot/cm². However, arrayed

Art Unit: 1634

spots of high density wherein the density is about 10,000 spot/cm² were well known in the art at the time the claimed invention was made as taught by Fodor et al (Column 20, lines 27-39). Furthermore, Fodor et al teach that high density arrays (e.g. 10,000 spot/cm²) were preferred in methods for assaying biopolymer binding because they reduce the number of assays necessary and thereby increase the speed and accuracy of assay procedures and results (Column 2, lines 26-47). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the high density array of Fodor et al (e.g. 10,000 spot/cm²) to the arrayed biomolecules of Nova et al thereby providing a biochip which reduces the number of assays for the expected benefits of increased speed and accuracy of assay procedures and results as taught by Fodor et al (Column 2, lines 26-47).

5. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nova et al (U.S. Patent No. 6,284,459 B1, filed 5 September 1996) view of Kercso et al (U.S. Patent No. 6,132,685, filed 10 August 1998) as applied to Claim 8 above and further in view of Drmanac et al (U.S. Patent No. 6,297,006, filed 4 March 1997).

Regarding Claim 31, Nova et al and Kercso et al teach the method of Claim 8 as discussed above wherein the amount of biopolymer is stored in the integrated circuit memory but they do not further teach normalizing a detected amount.

However, normalization was well known in the art at the time the claimed invention was made as taught by Drmanac et al who teach that normalization of the detected amount of biopolymers bound to a sample with the amount of biopolymers on each spot is necessary to properly integrate information from different experiments (Example 12, Column 21, lines 23-

Art Unit: 1634

35). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the normalization of Drmanac et al to the use of the Nova et al and Kercso et al biochip for the expected benefit of providing for accurate comparison of different hybridization experiments as taught by Drmanac et al (Column 21, lines 23-26).

Response to Arguments

6. Applicant argues that none of the previously cited references teach or suggest the instantly claimed "detected amount". The argument has been considered but is not found persuasive for the reasons stated above. Briefly, the product claims are not defined by the method of making the product. As such, the instantly claimed produces are either the same or obvious over the cited references. Furthermore, the method of making the biochip does not require a detection step, but merely requires that information including a detected amount of the biopolymer be written into the memory. As discussed above, the detected amount is obvious in view of the testing and determination of biopolymer of Nova et al.

Applicant argues that the instant biochip possess information concerning the detected amount of biopolymers such that variations of spotted amounts can be corrected. The argument has been considered but is not found persuasive because the product claims are not limited to detecting an amount after spotting, but merely a detected amount. Furthermore, variations of spotted amounts and/or correction of variations are not limitations of the claims. Therefore, the arguments are not commensurate in scope with the claims.

Art Unit: 1634

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878 until 13 January 2004. Starting 14 January 2004, the examiner's phone number will be (517) 272-0741. The examiner can normally be reached on 6:00 TO 3:30 Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
November 26, 2003